

REMARKS:

In the Office Action dated June 22, 2010, claims 1-3, 5-12, 15, 16, and 18-24, in the above-identified U.S. patent application were rejected. Reconsideration of the rejections is respectfully requested in view of the above amendments and the following remarks. Claims 1-3, 5, 7-12, 15, 16, and 18-24 remain in this application and claims 4, 6, 13, 14, and 17 have been canceled. The amendments to claims 1, 20, 21 and 22 are supported by original claims 2 and 6 thus do not raise new issues.

Claims 1-3, 15, 16 and 20-23 were rejected under 35 USC §103(a) as unpatentable over Kiliaan (WO 0184961) in view of della Valle (US 4,595,680). As discussed in applicant's prior response, unlike the present invention, Kiliaan's preparation is not a solid matrix. However, in order to further clarify the presently claimed invention, claims 1, 20, 21 and 22 have been amended to recite the limitations of claims 2, 6, 23 and/or 24 (i.e. 15 to 40 % by weight phosphatidyl serine and wherein the matrix is encapsulated with a water-containing coating). Applicants respectfully point out that Example 1 in Kiliaan discloses 14.4% phosphatidyl serine, Kiliaan does not suggest or disclose a wax component in the amount of 5 to 20 weight % and Kiliaan does not suggest or disclose a solid matrix encapsulated in a water containing coating. The specific encapsulated matrix according to the present claims allows for very stable formulations despite the water-containing coating. As mentioned on page 3, fourth paragraph, of the present application, one object of present invention is to provide phospholipid containing matrices having adequate stability even in an encapsulated state. As stated on page 3,

last paragraph, of the present application, the matrix according to the present invention which contains phosphatidyl serine and phosphatidyl choline is extremely stable towards hydrolysis and degradation. This is exemplified by the examples in the present application. According to examples 1 to 3, even after 12 months 96 weight-% of original phosphatidyl serine was still present in the matrix encapsulated in a soft gelatin capsule. In contrast to examples 1-3, in the formulations according to comparative examples 4 to 6, the amount of phosphatidyl serine after 12 months was in the range from 62 to 70 weight %. These comparative examples were prepared according to DE 199 17 249 which is referenced on page 2, last full paragraph, of the present application. Thus, the encapsulated matrices of the present invention result in higher stabilities than can be obtained with the system according to DE 199 17 249 which was specifically designed to stabilize phosphatidyl serine against hydrolysis.

della Valle does not cure the above discussed deficiencies in Kiliaan as della Valle does not suggest or disclose a solid matrix comprising 15 to 40 weight-% phosphatidyl serine, 1 to 90 weight-% phosphatidyl choline, 20 to 50 weight-% of a fatty component and 5 to 20 weight-% of wax component, wherein the matrix is encapsulated with a water-containing coating. Oral pharmaceutical composition (a) of Example 5 in della Valle uses phosphatidyl serine (about 33 weight-%), with about 67 weight-% vegetable oils and 0.2 weight-% bees wax. Thus in della Valle, phosphatidyl choline is completely missing and the amount of bees wax is significantly less than in the presently claimed invention. The same applies to the amount of the fatty component.

Neither Kiliaan or della Valle suggest the use of 1-94% by weight of a wax component as in the present invention. Since 99.75% of della Valle's components are liquid, della Valle's matrix would clearly not be solid. In view of the above amendments and discussion, applicants contend that the combination of Kiliaan and della Valle does not render the presently claimed invention obvious and request that this rejection be withdrawn.

Claims 1-3, 5, 15, 16, 19 and 20-23 were rejected under 35 USC §103(a) as unpatentable over Kiliaan (WO 0184961) in view of della Valle (US 4,595,680) further in view of Patel (US 6,294,192). Patel was cited for the disclosure of solubilizers such as polyethylene glycol. Patel is directed to a pharmaceutical composition for delivering hydrophobic agents. Patel's preparation is intended to form an aqueous dispersion after administration and can be administered in the form of a solid dispersion (col. 26, lines 2534). Patel does not suggest or disclose that it is possible or desirable to prepare a stable, solid matrix containing phosphatidyl choline and 15 to 40 % by weight phosphatidyl serine, wherein the matrix is encapsulated with a water-containing coating and does not suggest the components and ratios recited in the present claims which are necessary to produce such a matrix. Therefore, Patel does not cure the above discussed deficiencies in Kiliaan and della Valle and applicants request that this rejection be withdrawn.

Claims 1, 6-12, 18, 22 and 24 were rejected under 35 USC §103(a) as unpatentable over Kiliaan (WO 0184961) in view of della Valle (US 4,595,680) further in view of Winston Jr. (US 5,342,626). Winston Jr. was cited for the disclosure of encapsulating materials such as gelatin and nongelatin polymers. Winston Jr. does

not suggest or disclose that it is possible or desirable to prepare a stable, solid matrix containing phosphatidyl serine and phosphatidyl choline, which can be encapsulated with a water-containing coating, and does not suggest the components and ratios recited in the present claims which are necessary to produce such a matrix. Therefore, Winston Jr. does not cure the above discussed deficiencies in Kiliaan and della Valle and applicants request that this rejection be withdrawn.

Applicants respectfully submit that all of claims 1-3, 5, 7-12, 15, 16, and 18-24 are now in condition for allowance. If it is believed that the application is not in condition for allowance, it is respectfully requested that the undersigned attorney be contacted at the telephone number below.

In the event this paper is not considered to be timely filed, the Applicant respectfully petitions for an appropriate extension of time. Any fee for such an extension together with any additional fees that may be due with respect to this paper, may be charged to Counsel's Deposit Account No. 02-2135.

Respectfully submitted,

By /Monica Chin Kitts/
Monica Chin Kitts
Attorney for Applicant
Registration No. 36,105
ROTHWELL, FIGG, ERNST & MANBECK
1425 K. Street, Suite 800
Washington, D.C. 20005
Telephone: (202) 783-6040

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